

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR)	
STERILE PRODUCTS, LLC, and ENDO)	
PAR INNOVATION COMPANY, LLC,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 23-358-GBW-SRF
)	
BAXTER HEALTHCARE)	
CORPORATION,)	
)	
Defendant.)	

REPORT AND RECOMMENDATION

Pending before the court is the parties’ claim construction dispute regarding two disputed terms in United States Patent Nos. 9,993,520 (“the ’520 patent”), 11,135,265 (“the ’265 patent”), and 11,207,372 (“the ’372 patent;” collectively, the “Asserted Patents”).¹ The Asserted Patents are generally directed to ready-to-use (“RTU”) vasopressin formulations that can be stored for extended periods of time. Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, “Plaintiffs”) brought this patent infringement action against defendant Baxter Healthcare Corporation (“Baxter”) on March 29, 2023, alleging that Baxter’s Vasopressin in 0.9% Sodium Chloride Injection product (“Baxter’s Product”) infringes the Asserted Patents. (D.I. 1) Following a review of the parties’ joint claim construction brief and associated materials (D.I. 105; D.I. 106), and after consideration of the arguments presented at the *Markman* hearing held on September 4, 2024, I recommend that the court adopt the following constructions for the disputed terms for the reasons set forth below:

¹ Consistent with the parties’ joint claim construction brief, the court cites the disclosures as found in the ’520 patent for ease of reference. (D.I. 105 at 1 n.1)

Term	Recommended Construction
“providing . . . storing . . . administering” (’520 patent, claims 1, 4-9, & 13; ’372 patent, claims 1-3 & 6-13)	Construction necessary only because the parties dispute the plain and ordinary meaning, which is that the steps must occur in this order: providing, then storing, then administering.
“unit dosage form” (’520 patent, claims 1, 4-9, & 13; ’265 patent, claims 1-4, 7-14, & 16; ’372 patent, claims 1-3 & 6-13)	No construction necessary.

I. BACKGROUND OF THE TECHNOLOGY

Vasopressin is a peptide hormone that acts to regulate water retention in the body and increase blood volume. (’520 patent, col. 4:63-5:8) In higher concentrations, vasopressin raises blood pressure by constricting blood vessels throughout the body. (*Id.*, col. 5:8-9) Vasopressin can be used clinically to treat sepsis, cardiac conditions, and low blood pressure, among other conditions. (*Id.*, col. 7:12-29)

Vasopressin formulations can be used clinically to treat patients suffering from dangerously low blood pressure. (*Id.*, col. 8:24-26) Vasopressin formulated as an aqueous solution can be diluted or reconstituted prior to use. (*Id.*, col. 8:59-61) In prior art formulations, once the vasopressin was diluted or reconstituted into unit dosage form, the solution could be refrigerated for stability for about one day, after which the solution would begin to degrade and become unsuitable for use. (*Id.*, col. 8:61-65; 67:28-32) The Asserted Patents are directed to premixed vasopressin formulations and methods of administering those formulations that include stabilizing polymer agents to prolong the shelf life of the diluted RTU formulations beyond one day and up to two years under refrigeration. (*Id.*, Abstract; col. 52:56-58)

Plaintiffs allege that Baxter’s Vasopressin in 0.9% Sodium Chloride Injection product (“Baxter’s Product”) infringes claims 1, 4-9, and 13 of the ’520 patent, claims 1-3 and 6-13 of the ’372 patent, and claims 1-4, 7-14, and 16 of the ’265 patent (collectively, the “Asserted

Claims”). (D.I. 94 at A-1, A-3) The disputed claim terms are found in the Asserted Claims.

Independent claim 1 of the ’520 patent is exemplary and recites:

A method of increasing blood pressure in a human in need thereof, the method comprising:

- a) providing a unit dosage form for intravenous administration, wherein the unit dosage form comprises:
 - i) from about 0.1 units/mL to about 1 unit/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
 - ii) from about 1 mM to about 10 mM acetate buffer;
 - iii) 0-2% vasopressin degradation products;
 - iv) sodium chloride; and
 - v) water; and
- b) storing the unit dosage form for at least about 24 hours at from about 0.1 units/ml to about 1 unit/ml of vasopressin or a pharmaceutically-acceptable salt thereof; and
- c) after storing, administering the unit dosage form to the human by intravenous administration, wherein the unit dosage form that is administered to the human comprises from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof; wherein:

the unit dosage form has a pH of 3.4 to 3.8; the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and the human is hypotensive.

(’520 patent, col. 175:32-58)

II. LEGAL STANDARD

The purpose of the claim construction process is to “determin[e] the meaning and scope of the patent claims asserted to be infringed.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370, 388-90 (1996). Construing the claims of a patent presents a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326 (2015) (citing *Markman*, 52 F.3d at 977-

78). An actual dispute regarding the proper scope of a claim term must be resolved by a judge, as opposed to the jury. *Markman*, 52 F.3d at 979.

“[T]here is no magic formula or catechism for conducting claim construction.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 (Fed. Cir. 2005). Instead, the court may attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.* The words of the claims “are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312-13 (internal citations and quotation marks omitted). If the meaning of a claim term is not readily apparent, the court considers sources including “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004).

“It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips*, 415 F.3d at 1312 (internal quotation marks omitted). Accordingly, “the claims themselves provide substantial guidance as to the meaning of particular claim terms.” *Id.* at 1314. Claim terms are typically used consistently throughout the patent, and “usage of a term in one claim can often illuminate the meaning of the same term in other claims.” *Id.* Also, “[d]ifferences among claims can also be a useful guide For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted).

The claims must be read in view of the specification, which “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). The specification may also contain a disclaimer or disavowal of claim scope. *Id.* However, “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted). The specification “is not a substitute for, nor can it be used to rewrite, the chosen claim language.” *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman*, 52 F.3d at 980. The prosecution history, which is “intrinsic evidence . . . consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

In some cases, courts “will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the

meaning of a term in the relevant art during the relevant time period.” *Teva*, 574 U.S. at 331.

Extrinsic evidence “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. Expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.”

Phillips, 415 F.3d at 1318. Nonetheless, “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Although extrinsic evidence “may be useful to the court,” it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999).

III. ANALYSIS

I recommend that the court adopt the parties’ agreed-upon constructions for the following three terms in the Asserted Patents:

CLAIM TERM	AGREED-UPON CONSTRUCTION
“about 1 mM to about 10 mM acetate buffer” (’520 patent, claims 1, 4-9; ’265 patent, claims 1-4, 7-14)	Plain and ordinary meaning, which is “a solution containing a mixture of acetic acid and acetate, with a total concentration of about 1 mM to about 10 mM, that is capable of resisting change in pH upon the addition of acidic or basic substances”
“about 10 mM acetate buffer” (’520 patent, claim 13; ’265 patent, claim 16)	Plain and ordinary meaning, which is “a solution containing a mixture of acetic acid and acetate, with a total concentration of about 10 mM, that is capable of resisting change in pH upon the addition of acidic or basic substances”

“acetate buffer” (’372 patent, claims 1-3 & 6-13)	Plain and ordinary meaning, which is “a solution containing a mixture of acetic acid and acetate that is capable of resisting change in pH upon the addition of acidic or basic substances”
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(D.I. 94 at B-1) The parties dispute the meaning of two terms in the Asserted Patents. The court’s recommendations for the proper constructions of these two terms are set forth below.

A. “providing . . . storing . . . administering”

Plaintiffs’ proposal	Baxter’s proposal	Recommended construction
No construction necessary. In the alternative, plain and ordinary meaning, which is the claimed method includes making the unit dosage form available for use, storing it prior to use, and using it by intravenously administering it to the patient.	Construction necessary only because the parties appear to dispute the plain and ordinary meaning, which is that the steps must occur in this order: providing, then storing, then administering.	Construction necessary only because the parties dispute the plain and ordinary meaning, which is that the steps must occur in this order: providing, then storing, then administering.

The parties dispute whether the “providing” and “storing” steps of the Asserted Claims must be performed in the order they are listed in the claim language and whether the unit dosage form may be provided and stored multiple times before being administered. The parties agree that the “administering” step must occur after the “providing” and “storing” steps. (D.I. 105 at 14-16) The intrinsic evidence supports Baxter’s position that the steps occur in their written order, and that the time between the manufacturer’s “provision” of the diluted RTU unit dosage form and the administration of that unit dosage form to a patient constitutes the “storing” step. During the *Markman* hearing, Plaintiffs conceded that only extrinsic evidence affirmatively supports their proposed construction, which allows the “storing” step to occur before the “providing” step and indicates that these two steps may be performed multiple times prior to administration. (9/4/2024 Tr.)

Generally, the steps of a method claim are not construed to be performed in the order written unless the method steps recite a specific order. *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001). However, the method steps must be performed sequentially when (1) “as a matter of logic or grammar, [the steps] must be performed in the order written,” or (2) the specification “directly or implicitly requires such a narrow construction.” *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369-70 (Fed. Cir. 2003). Both of these considerations support Baxter’s position that the “providing” step must occur before the “storing” step in the Asserted Claims.

Here, the antecedent references in the Asserted Claims require the three steps to be performed in the order recited as a matter of logic and grammar. *See Intellectual Ventures I LLC v. AT&T Mobility LLC*, C.A. No. 12-193-LPS *et al.*, 2015 WL 1393386, at *29 (D. Del. Mar. 24, 2015) (“Because the antecedent references in each successive step make clear the prior step serves as its precursor, the claim requires the method steps be performed in their sequence as listed in the claim.”). The “providing” step recites “providing *a* unit dosage form,” followed by the “storing” step’s requirement for “storing *the* unit dosage form.” (’520 patent, col. 175:34-52) The Federal Circuit has explained that “when the current step of a method claim refers to a previous step using the definite article ‘the,’ the claim language indicates that the previous step occurs sequentially before the current step.” *Medtronic, Inc. v. Teleflex Life Scis. Ltd.*, 2024 WL 1208642, at *3 (Fed. Cir. Mar. 21, 2024) (citing *Wi-Lan, Inc. v. Apple, Inc.*, 811 F.3d 455, 462 (Fed. Cir. 2016) (“Subsequent use of the definite articles ‘the’ or ‘said’ in a claim refers back to the same term recited earlier in the claim.”)). As a matter of logic and grammar, therefore, “the” unit dosage form stored in step (b) refers to the unit dosage form that was previously provided in step (a). *See Techno View IP Inc. v. Oculus VR LLC*, C.A. No. 17-386-VAC-CJB, 2018 WL

4141032, at *2-3 (D. Del. Aug. 30, 2018) (holding that antecedent basis language in the method steps conclusively required those steps to be performed in the order recited as a matter of logic and grammar).

Plaintiffs suggest that the court should disregard the antecedent basis in the “providing” step and construe steps (a) and (b) in a manner that would allow them to be performed multiple times in any order, while maintaining that the court should require step (c) to be performed in the order it is written. (D.I. 105 at 38-39) The Federal Circuit rejected a similar argument as illogical in *Hytera Communications, Ltd. v. Motorola Sols., Inc.*, 841 F. App’x 210, 218 (Fed. Cir. 2021). There, the parties disputed whether the claimed “preparing” step must come before the “determining” step, even though they agreed that the “transmitting” step must be performed last. *Id.* The Federal Circuit determined that the “preparing” and “determining” steps must be performed in that order, as recited in the claims, because each step of the method provided an antecedent basis for the steps that followed. *Id.* The Federal Circuit also explained that, “as a matter of logic, we reject Hytera’s position that we should construe [the asserted claim] as requiring four of its five steps to be performed in the order they are written, but we should disregard the antecedent basis in the ‘preparing’ step and allow that one step to be performed out of order.” *Id.*

The use of ordinals in the claim language further confirms that the method steps must be performed sequentially as a matter of logic and grammar. In *Amgen Inc. v. Sandoz Inc.*, the Federal Circuit held that the claim language logically required steps “lettered (a) through (g)” to be performed in sequence. 923 F.3d 1023, 1028 (Fed. Cir. 2019). Similarly, each step of the

claimed method in the '520 patent is preceded by an ordinal:² step (a) requires “providing a unit dosage form;” step (b) recites “storing the unit dosage form;” and step (c) requires “administering the unit dosage form” after the storing. ('520 patent, col. 175:34-52) The ordinal labeling of steps (a), (b), and (c) provides additional support, in combination with the antecedent basis argument, for limiting the order of performance of the claimed method steps. *See Intellectual Ventures II, LLC v. AT&T Corp.*, 2015 WL 4138590, at *14 (W.D. Tex. July 8, 2015) (concluding that alphabetic designations preceding method steps indicated an intended order of performance).

Because the claim language demonstrates the order of the steps, the court “need not look further into the specification” or the prosecution history. *Hytera Commc'ns*, 841 F. App'x at 218-19. Nonetheless, the balance of the intrinsic record provides additional support for Baxter's proposed construction limiting the claimed steps to the order in which they are recited. *See Azurity Pharms., Inc. v. Amneal Pharms., LLC*, 2022 WL 3691392, at *10 (D.N.J. Aug. 25, 2022) (observing that the Federal Circuit generally analyzes the specification even where the claim language itself supports limiting the claimed method steps to the recited order). There is no dispute that 110 embodiments disclosed in the specification include the step of “providing,” and the “providing” step is listed before the “storing” step in each of those embodiments. (D.I. 105 at 20-21, 37-38; '520 patent, cols. 16:4-48:35) The absence of embodiments showing the steps being performed in a different order supports the court's construction of the claim language to require performance of the steps in the order that is written. *Hytera*, 841 F. App'x at 219

² Unlike the '520 patent, the method steps in the '372 patent are not preceded by ordinals. (D.I. 94, Ex. 3 at cols. 179-180) However, the same considerations of the plain meaning of the claim language, the antecedent basis wording, and the embodiments in the specification support the court's recommended construction.

(concluding that claim steps were to be performed in the order they were written where the embodiments were consistent with the plain meaning of the claim in the order it was written).

The prosecution history of the '520 patent further supports the recommendation that the claimed method steps must be performed in the order recited. In an interview summary dated February 12, 2018, Plaintiffs proposed “adding a step of storing the vasopressin for at least about 24 hours *after* providing the unit dosage form and before administering” to overcome an obviousness rejection over the prior art. (D.I. 94-9 at 10) (emphasis added). The examiner allowed the patent with this proposed amendment, reasoning that “[d]iluting the vasopressin . . . and storing the vasopressin in diluted form for at least about 24 hours prior to administration is not obvious” over the prior art. (*Id.* at 18) This statement clarifies that the length of storage is measured from the time the unit dosage form is provided in diluted form to the time it is administered. *See Fraser v. High Liner Foods (USA), Inc.*, 337 F. App’x 883, 888 (Fed. Cir. 2009) (concluding that claim language and statements made during prosecution confirmed that the claimed steps were required to be performed in the order recited).

Plaintiffs rely on the Federal Circuit’s decision in *Altiris, Inc. v. Symantec Corp.* in support of their position that antecedent basis language and preferred embodiments are not enough to impose a required sequence for performing the method steps. 318 F.3d 1363, 1369-71 (Fed. Cir. 2003). But *Altiris* is distinguishable from the intrinsic record in this case because the specification discussed only a single preferred embodiment, and there was no prosecution history “indicating a surrender of any other order of steps.” *Id.* at 1371. Moreover, there was consensus between the parties’ experts that the purpose of the invention could be achieved regardless of whether the claimed “setting” step was performed before, during, or after the “booting normally” step. *Id.* In contrast, the written description of the Asserted Patents includes a large volume of

preferred embodiments that all recite the “providing” step occurring before the “storing” step, the applicant expressly stated during prosecution that the “storing” step comes after the “providing” step, and there is no agreement between the parties’ experts on this term.

Plaintiffs’ contention that the unit dosage form can be “provided” numerous times between the time of manufacture and the time of administration is supported by an expert declaration explaining the process for distributing and storing drugs in a hospital and/or pharmacy setting. (D.I. 105 at 35) However, the common specification of the Asserted Patents is not directed to the movement of pharmaceuticals throughout medical facilities. Instead, the focus of the claimed invention is on the extended shelf life of RTU unit dosage forms of vasopressin. (’520 patent, col. 48:36-56, 52:42-62) Plaintiffs’ proposed construction runs the risk of “cloud[ing] the issue” where, as here, nothing in the intrinsic record supports the concept of multiple “providing” and “storing” steps. *See Tuna Processors, Inc. v. Hawaii Int’l Seafood, Inc.*, 327 F. App’x 204, 210 (Fed. Cir. 2009).

Because the meaning of this disputed term is unambiguous based on the intrinsic evidence, the court does not consider the parties’ expert declarations or other extrinsic evidence. *See Wi-Lan*, 811 F.3d at 462 (“Extrinsic evidence may not be used to contradict claim meaning that is unambiguous in light of the intrinsic evidence.” (internal citations and quotation marks omitted)). In accordance with the foregoing analysis, I recommend that the court adopt Baxter’s proposed construction based on the language and structure of the Asserted Claims, as supported by the embodiments in the specification and statements made during prosecution. *See Hytera Commc’ns*, 841 F. App’x at 219.

B. “unit dosage form”

Plaintiffs’ proposal	Baxter’s proposal	Recommended construction
No construction necessary. In the alternative, plain and ordinary meaning, which is a unit dosage form as recited in the claim.	Construction necessary only because the parties appear to dispute the plain and ordinary meaning, which is a unit dosage form that has the properties recited in the claim at all times prior to being administered.	No construction necessary.

As is evident from the parties’ competing constructions, which recite the claim term itself, there is no dispute about the meaning of the words “unit dosage form.” Baxter’s proposal seeks to clarify that the unit dosage form has the properties recited in the claim at all times prior to being administered. (D.I. 105 at 61-66) But it is not apparent from the intrinsic record that such clarification is necessary. *See Summit 6, LLC v. Samsung Elecs. Co., Ltd.*, 802 F.3d 1283, 1291 (Fed. Cir. 2015) (“Because the plain and ordinary meaning of the disputed claim language is clear, the district court did not err by declining to construe the claim term.”).

The court need not impose Baxter’s proposed temporal limitation on the claim language where, as Baxter concedes, “[t]he use of ‘*the* unit dosage form’ in both the ‘storing’ and ‘administering’ steps confirms that they utilize the same unit dosage form” described in the preceding step of “providing *a* unit dosage form.” (D.I. 105 at 62) (emphasis added). Because the plain and ordinary meaning of the term is apparent from the language of the claims themselves, no construction is needed. *See Aventis Pharms. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013) (“There is a heavy presumption that claim terms are to be given their ordinary and customary meaning.”). Plaintiffs do not meaningfully dispute Baxter’s position that the properties of the unit dosage form remain the same during the steps leading up to administration: “Plaintiffs do not take the position that the claimed unit dosage form has

‘different properties’ depending on the step of the claim. Instead, Plaintiffs assert that the plain language of the claims is straightforward—the unit dosage form has the properties *as recited in the claim.*” (D.I. 105 at 69) (emphasis in original).

Baxter’s proposal risks introducing ambiguity and confusion. As discussed, the plain language of the claim establishes that the “unit dosage form” has the same properties throughout all three steps of the recited method. But by suggesting the “unit dosage form” must have the same properties recited in the claims “at *all times* prior to being administered,” Baxter’s proposal risks exceeding the scope of the recited method steps of “providing,” “storing,” and “administering.” There is no intrinsic support for this approach. *See ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1326 (Fed. Cir. 2012) (concluding that the plaintiff’s proposed construction “erroneously reads limitations into the claims and the district court properly rejected that construction and resolved the dispute between the parties.”).

IV. CONCLUSION

For the reasons set forth above, I recommend that the court construe the disputed terms as follows:

Term	Recommended Construction
“providing . . . storing . . . administering” (’520 patent, claims 1, 4-9, & 13; ’372 patent, claims 1-3 & 6-13)	Construction necessary only because the parties dispute the plain and ordinary meaning, which is that the steps must occur in this order: providing, then storing, then administering.
“unit dosage form” (’520 patent, claims 1, 4-9, & 13; ’265 patent, claims 1-4, 7-14, & 16; ’372 patent, claims 1-3 & 6-13)	No construction necessary.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation.

Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court's website, <http://www.ded.uscourts.gov>.

Dated: September 6, 2024


Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE